DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administratio

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San Francisco District
1431 Harbor Bay Parkway
Alameda. CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: FEI 1000522954

July 21, 2003

Masamitsu Furuta, President/CEO
IMP Foods, Inc.
1021 South Railroad Avenue
San Mateo, California 94402

WARNING LETTER

Dear Mr. Furuta:

On April 1, 2, and 7, 2003, we inspected your seafood processing facility, located at 1021 South Railroad Avenue, San Mateo, California. We found that you have serious deviations from the Seafood HACCP regulation in Title 21, Code of Federal Regulations, Part 123 (21 C.F.R. Part 123). In accordance with 21 C.F.R. § 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated, ready-to-eat fish and fishery products, e.g., fresh and smoked salmon, sea urchin, and your refrigerated histamine forming fish, e.g., tuna, Yellowtail, and Spanish Mackerel, are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov. See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls

Guidance, 3rd edition, June 2001. We listed the deviations on a Form FDA-483 and discussed them with you at the conclusion of the inspection. We are enclosing a copy of the Form FDA-483 for your reference. Your serious HACCP deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. However, your firm's HACCP plan for Category ABC (Pathogen, Histamine, and Clostridium botulinum hazards due to reduced atmosphere packaging) for refrigerated vacuum packaged fish and fishery products, lists a critical limit of "Temperature and time range of shipment" at the Receiving critical control point (CCP) that is not adequate to control Clostridium botulinum growth and toxin formation as a result of time/temperature abuse during transit. FDA recommends that the temperatures of vacuum packaged raw fish be maintained strictly at or below 38°F from packing to consumption. The use of time temperature integrator (TTI) on each consumer package is recommended and the appropriate critical limit would be that each package is affixed with an activated TTI. Visual monitoring of a representative number of cartons would be an appropriate monitoring procedure for this critical limit.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures and the frequencies thereof for each critical control point, to comply with 21 CFR 123.6(c)(4).

   (a) However, your firm's HACCP plans for Categories AB (Pathogen and Histamine hazards for scombroid species) lists a monitoring frequency at the Receiving critical control point that is not adequate to control histamine formation as a result of time/temperature abuse. The plan does not indicate how many cases will be examined for the presence of ice or cooling media during the receipt of the product.

   (b) However, your firm's HACCP plans for Categories AB (Pathogen and Histamine hazards for scombroid species), and

ABC (Pathogen, Histamine, and Clostridium botulinum hazards due to reduced atmosphere packaging) list a monitoring frequency at the Cold Storage CCP that is not adequate to control pathogen growth and histamine formation. During the inspection, we observed tuna fillets/loins being stored in your refrigerated coolers without ice or other cooling media. For refrigerated storage of scombroid species, FDA recommends maintenance of refrigerated storage coolers at 40°F or below, with continuous monitoring of the temperature. You may either monitor the cooler temperature by means of a temperature data recorder or an alarm system or monitor the adequacy of ice or cooling media on the product at least twice a day.

3. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not adequately follow the monitoring procedures of checking for the adequacy of ice or other cooling media to control histamine formation and pathogen growth, and checking the product temperature or the presence of time/temperature indicators at the Receiving CCP listed in your HACCP plan ABC (Pathogen, Histamine, and Clostridium botulinum hazards due to reduced atmosphere packaging). For example, on April 2, 2003, your firm received [redacted] cases of fresh vacuum packaged Yellowtail fillets at 3:30 a.m., [redacted] of which were placed directly into the refrigerated cooler without being checked for adequacy of ice or cooling media. Although [redacted] cases were left in the packing area, these were not checked until about one hour later.

4. You must implement the record keeping system that you have listed in your HACCP plans, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Receiving and Storage critical control points as listed in your plans for Category AB (Pathogen and Histamine hazards for scombroid species) and ABC (Pathogen, Histamine, and Clostridium botulinum hazards due to reduced atmosphere packaging). Your firm received shipments of fish on March 8, 17, 22, and 29, 2003, and approximately [redacted] shipments of fish from [redacted], including vacuum packaged Yellowtail fillets, between February 1 and March 31, 2003, but failed to document the results of monitoring the Receiving CCP.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor key sanitation areas with sufficient frequency to ensure control of cross-contamination from insanitary objects to food [21 CFR 123.11(b)(3)] as evidenced by poor employee practices that we observed during the inspection. For example, FDA observed an employee who was in the process of filleting fresh tuna, wearing cotton gloves which contained holes and appeared to be unclean, and this employee was directly handling fresh tuna intended for raw consumption. Another employee was observed conducting multiple tasks and directly handling the exposed tuna product with his bare hands without washing and sanitizing his hands in between the tasks.

6. You must maintain sanitation control records that, at a minimum, document that your monitoring and corrections are adequate, to comply with 21 CFR 123.11(c). However, your sanitation control records which must document all eight areas of sanitation conditions and practices during processing, were missing for the days of March 8, 17, 22, and 29, 2003.
   Moreover, your sanitation control record form is deficient in that it does not address the following key areas of sanitation, as required by 21 CFR 123.11(b): maintenance of hand washing, hand sanitizing, and toilet facilities [21 CFR 123.11(b)(4)]; protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants [21 CFR 123.11(b)(5); proper labeling storage, and use of toxic compounds [21 CFR 123.11(b)(6)]; control of employee health conditions that could result in microbiological contamination of food, food packaging materials, and food contact surfaces [21 CFR 123.11(b)(7)]; and exclusion of pests from the food plant [21 CFR 123.11(b)(8)].

7. You must have and implement written verification procedures for ensuring that the fish and fishery products that you import were processed in accordance with the seafood HACCP regulation (21 CFR Part 123), to comply with 21 CFR 123.12(a)(2).

(a) However, your firm does not have product specifications for fresh and frozen Yellowtail fillets in vacuum packages, as required under 21 CFR 123.12(a)(2)(i).

(b) However, your firm performed an affirmative step, as required under 21 CFR 123.12(a)(2)(ii), of Option D to maintain on file a copy, in English, of the foreign processor's HACCP plans for Yellowtail Fillets, manufactured by [redacted] which was inadequate. Specifically, [redacted] HACCP plan did not list the food safety hazard of pathogen growth and toxin formation including Clostridium botulinum and histamine formation; and [redacted] HACCP plan did not list the food safety hazard of pathogen growth and toxin formation including Clostridium botulinum toxin formation.

Sufficient time has passed, since our inspection of April 2003 and our presentation of the FDA 483 Inspectional Observations to you, to correct the violations at your facility. If you have not made corrections, you must immediately take appropriate steps to correct the violations. We may initiate regulatory action without further notice if you do not correct these problems. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things that you are doing to correct the deviations. You may wish to include in your response documentation such as copies of your HACCP plans, temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation and the Good Manufacturing Practice regulation (21 C.F.R. Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosures:

Form FDA 483
Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001

cc: Glenn Y. Sakata, General Manager